Transcript

Good afternoon, and thank you for joining the ClinicalTrials.gov Modernization and Beta Sites Progress webinar. I'm Anna Fine, and I'm currently the acting director for ClinicalTrials.gov, and I'll serve as your moderator for today as well as provide an overview of the modernization effort.

Before we begin, I'd like to remind attendees this webinar is being recorded. The recording and the slides will be made available in a few weeks. All participants are muted during this presentation. You can send questions through the Q&A feature using the Q&A feature within Zoom, and we will be collecting your questions for our speakers to respond to them live at the end of the presentation. Let's review the topics that we'll be covering today.

The topics that we're going to cover include an overview of the modernization effort; and I'll be joined shortly by two of my fellow colleagues who will share updates on the beta Protocol Registration Results System and the ClinicalTrials.gov Beta website. The three of us will take your questions live, and we'll be reading the ones that are submitted through the Q&A box.

We're really excited to be sharing updates on all the effort we've put in this year into making ClinicalTrials.gov better for you.

Before we dive into the betas, let's review the stakeholders that ClinicalTrials.gov serves. First, we aim to support the sponsors and the investigators of trials who submit the information via the Protocol Registration and Results System, known as the PRS. This information is then retrievable at the ClinicalTrials.gov website for patients, health care professionals, and data researchers. And we are simultaneously building a more modern PRS and ClinicalTrials.gov website. The program is part of the National Library of Medicine. We do not create the content; we simply provide the electronic shelves for the content to be retrievable.

Let's take a poll. How would you describe your role in relation to ClinicalTrials.gov? A pop-up should be appearing on your screen. Please select the best answer. We recognize there are many users of our website, such as librarians, statisticians, third-party data providers, or our government colleagues or organizations. So just please select the best . . . answer that pertains to you. Let's just give it a minute as people are responding. I can see about 80% of people responded. Great. Can we please share the results of the poll so everyone can see? Wonderful. It seems that we have a lot of sponsor and data submitters here and many that fall into that Other category. Thank you again for taking the poll. Whichever role you represent, we thank you for being here, and we acknowledge that the site is to be accessible by all.

It was timely for us to launch the modernization effort to accommodate the evolving studies and align with advances in technology. I'd like to reinforce that any changes are aimed to improve the user experience by upgrading the technical infrastructure and to support the existing regulatory and policy framework. ClinicalTrials.gov has over 430,000 studies available.

That is a lot of data to manage and for you to search. Therefore, optimizing the technology is important.

The modernization effort was intended to be a multiyear effort. The first year, we prioritized stakeholder engagement, soliciting input from users like you on the system needs. We then leveraged the information in year two to build a modernized website and PRS. As we conclude the third year of this effort, my colleagues will share our accomplishments in subsequent slides, as our proudest achievement was to make the modernized website and PRS Beta publicly available, so we can continue to build features with your input in our remaining years.

So you will hear from my colleagues about both the PRS and the ClinicalTrials.gov website and how you can navigate the beta sites and provide feedback. After you hear from my colleagues, we are eager to answer any questions you have about the modernization effort. So please type your questions in the Q&A box as we go along. And thank you again for your time. I'd like to introduce my colleague, the product owner for the PRS Beta site, Dr. Nachiket Dharker.

Thanks, Anna. Thanks, Anna. Hi, everyone. I'm very happy to share the updates on PRS modernization at ClinicalTrials.gov. As Anna Fine described, PRS is the submission system used by the record owners to create and submit the clinical study records to the ClinicalTrials.gov team for review. Once the record passes the QC review from our team, then they are made publicly available on ClinicalTrials.gov public site. So the data submitters interact with the PRS to create, update, and manage the records within their organization. The vision of the modernized PRS is that the users will experience a straightforward and efficient process to submit and manage the study records that they are submitting to us. And so as part of the PRS modernization, we are trying to improve the overall user experience and also making a lot of technology updates, such as improving the database architecture and developing enhanced infrastructure, which will make the system more efficient.

This year we have . . . So this year we have had three releases so far, all focused towards the PRS Beta Record List and the record management system. This is the chronology of the PRS Beta releases in the past. We had our first release in February this year, which included the new Record List and features that help data submitters to better manage their study records. Then in May we released further enhancements to the Record List, for example, inclusion of better filters, option to save views, and customize columns. Then in July we released more updates that were primarily aimed towards administrators within the organizations that help manage record for other users in the organizations. Specifically, these included two types of views, Planning View and the Public Site View.

The Record List in the first screen. . . . The Record List was the first screen that is displayed to the user when a user logs in to their account. It is the list of the study records associated with the user account and includes multiple columns, as you can see on the, in the screen capture, that provide information pertaining to the records. As part of the PRS modernization and the Record List modernization, the, the, we provided a modern and intuitive design to the Record

List. And now this Record List is much more flexible, and it provides much more flexibility to the users, who can customize their display based on their priorities and their needs and apply different filters to better manage their records. And, overall, we have received a positive feedback from our users. As a, as an example, this is one of the comments we received.

The Record List page includes an About drop-down menu to provide the resources to inform the users about the updates that, that are being made. There, there is an About PRS Beta option that provides screenshots and information to help users navigate through the system, and there is also a Release Notes option where we provide all the details of the releases that, that are happening chronologically, that provide users, again, more details of what, what we are updating throughout the years. And these release notes are publicly available, meaning they are available outside the log-in environment, and any user can get information on the updates in the public space.

So this is an example of how our new Record List is different from the Record List in, in the classic system. So I saw in the poll that many of you are PRS either data submitters or sponsors, so you may be familiar with this. But while the Record List in the classic system includes one search field here, and it includes checkboxes for select columns, on the other hand, in the new list we will have, we are providing search options for each and every column. And also there are advanced filters for many of these columns, which will make the record management and filtering and sorting easier for our users.

In order to highlight the important features of the new Record List, my colleague Stacey Arnold, who is a subject matter expert in our team, has recorded a few short videos to demonstrate important features of the PRS Beta. And these would serve to educate our users and help them use the new PRS. These recordings will be made available publicly, and the users will be able to access them from the public side once they are made available. Here we'll just play a sample segment from one of these recordings to give you an idea about them.

Within the pop-up box, you can use the up or down arrows to the right of column headers to move columns, or you can drag and drop columns to reorder them. Use the checkboxes to the left of column headers to select or deselect columns to display. You can hover over the "i" icons to see the brief descriptions of each column header. Once you click on the Save button, you'll see that the Record List header now reads, "Default View (Modified)." If you'd like to save the view, you can click on the dark blue Saved Views button . . . and select Save Current View As. I'll save my selected view as "PRS Beta Demo." Once I've named my view, you'll see that the header name has changed to match. When I return to the Saved Views menu, you'll se e that my saved view now appears at the bottom of the list.

So there are other such videos, there are other such videos that will be made available, as I said, on the public side for all of our users to access them.

So this slide shows the location of the Feedback button that is included on every screen. And we strongly encourage all our PRS users to use the, use and test the new screens as we are

developing them and provide us your feedback. We seriously consider and discuss all the feedback that we receive and, in fact, we rely on our users to help us improve the PRS.

Now that we have released the main parts of the Record List and the portfolio management system, as we are calling, calling them, and although we'll continue to make improvements to those and enhance those further, we have turned our focus now to developing the data entry screens for protocol registration, and starting with protocol registration it's, it's going to, we think, provide a lot of value to our users. And these protocol registration screen, because they have multiple sections and they have, they have a lot of dynamic fields with multiple validation rules, this is, this task is somewhat complicated, as you can imagine. This is a view of protocol registration screen on the classic system. Currently, if a user needs to perform data entry, they have to interact with multiple screens. So they first have to go to the Record Summary, then they open the main screen where they see different sections. Then they look at, they click on the Edit option next to each section that they want to complete to then start entering data, which we understand can be cumbersome to the users.

So in the new PRS or the beta PRS screen for protocol registrations, registration, we are planning to include a ref, left- rail navigation that would allow users to navigate through the different sections. And the data entry can be performed on the same screen on the right side of the screen, as shown in this screen capture.

This is one more example of the planned data entry screen for another section, where the users can provide information regarding the conditions or the focus of the study and provide any keywords associated with the study.

Another feature we are planning to introduce is the help drawer that will provide just-in-time help to the users and that, this drawer can be accessed using the "i," or information icon, that will be next to the data field. And the help drawer will include three types of help information or content. On top will be the brief description of the field. Then there will be additional info in an accordion, providing further explanation to understand the data field. And then there will be a second accordion that will include the data element definition. The brief description of the field and the additional information would be in plain language. And we hope that our users, you all, find it useful.

So these were some of the visuals of the protocol registration screens that we are currently working on. And because the different sections within the protocol registration are somewhat related and there are, as I said, lot of cross-validation involved, we are planning to release the complete protocol registration to the PRS sometime next year. Having said that, we are planning to iteratively release the protocol registration screens to our test system called PRS Test, which is a sandbox for PRS, and that, we are going to start doing that very soon. And our users will be able to view and play around with the screens, keep, keeping in mind that it is an iterative development, as I said. So, so many screens or sections or fields will be unavailable in the beginning, especially. But then as we start adding new features, you will start seeing more

functionality. The users will be able to see more progress throughout the course of development of the protocol registration screens on PRS Test system.

So this is a high-level summary, or visual, of the PRS Beta features that are already available, are in progress, or those that will be implemented in the future. Besides updates that I already discussed here, we are also, we have also achieved some important goals or milestones regarding modernizing the technology. And as I discussed, we are currently working on protocol registration. We are also working on how we can support secure log-in, besides working on some other technology aspects of modernization. And the future focus will of course be on results submission process, the QA/QC, and the account management experience. So with that, I will end my presentation here and, Anna, I will hand it back to you. Thanks.

Thank you, Dr. Dharker, to you and to your team for all the marvelous work on the PRS Beta. Very exciting to see all the progress and a preview of what's to come. Now I would like to introduce you to my colleague Christina Robinson, who is the product owner for the ClinicalTrials.gov Beta website. Christina.

Thank you, Anna. As you just heard, my name is Christina Robinson and I'm product owner for development of the new beta ClinicalTrials.gov website. I want to start today with a quick poll for all of you.

And I do want to mention it's perfectly fine to be honest, but I want you to let us know, Have you had the opportunity to visit the beta website? Yes or no? We'll talk just a little bit soon about how long that's been available and some of the changes that have been made. But it looks like we're getting pretty good responses to this. I'll wait just a few more seconds before we close and share the poll. Have you been able to visit the ClinicalTrials.gov website? Okay, I'm going to go ahead and wrap that up. So it looks like the majority of the folks on here with us today have been able to visit. We appreciate that. Thank you for doing so. Hopefully, you've been able to provide feedback. And for those of you who haven't seen it, we will give a demonstration shortly.

There we go. So similar to the development of the PRS, the beta website has had several updates over the last 10 months. It was launched initially in December of last year. That was what we call our minimum viable product, or MVP, and it was a basic version of the beta website so that we could put it out to all of you and start getting feedback. We want to make sure that what we build meets your needs as best as we possibly can. And since then, we've had three additional releases. Some of the things that we've made available or improved upon include refining the search results and the search functionality. We've made enhancements to the study record page. We made available download and a tabular view of the search results. And all of these things are based on the feedback that we're getting. We want to make sure that the most available features are out there the most, I'm sorry, the features that folks say they most need are available to, to test and to give feedback on. So now I want to give you an

overview of our modernization process for the beta website. Apologies. My slides are not responding in a very timely fashion.

There it is. So we made the beta website available in parallel to the exist, existing ClinicalTrials.gov. As I said before, that was in December of last year. We're currently in that second phase of development where we continue to build and make available additional features. This is going to continue for some time, but we do anticipate in the next year making the beta website the primary ClinicalTrials.gov experience. The classic ClinicalTrials.gov, the one that everyone already knows and most of you have probably used, will continue to be available in parallel, but it will be the secondary site experience. We're monitoring the feedback, we're monitoring usage, and we don't anticipate making the beta site primary until users can accomplish the majority of the tasks they need on the beta website. And then eventually, even further down the road, we will, we will need to retire the classic ClinicalTrials.gov. We are currently maintaining two systems, and I think that's necessary and the right thing to do, but that isn't really feasible over the long term. So please, as we're, we're making these new features available, continue to give us feedback and visit the website often. And we're going to move on.

At this time, I want to pause and share a prerecorded demonstration of the beta website.

Welcome. This is an overview of the beta ClinicalTrials.gov website. This video will highlight a few key features on how to conduct a search, the search results, and the study record page. I'll demonstrate these features and point out a few aspects of each of them as we go. Let me first guide you through how to use our new enhanced search, which combines the basic and advanced search features currently available on the classic ClinicalTrials.gov. The form starts with the title "I want to search for clinical studies" and the brief introduction, followed by an action bar, which sits just above the top of the search itself. This bar allows you to select from a long list of search criteria, which I'll show in just a moment; add all available fields, or reset to the default search form. At the far right is the Search button in dark blue. We've made action bars available on the home page, search results and study record pages, so you'll see them again shortly.

Under Select Fields, you can find all available search criteria. For this demonstration, let's search for studies that have study results and are NIH funded. I'm going to look for studies specific to Parkinson's Disease for this demonstration.

This is the card view of the search results. On the left-hand side, you'll see all of the filters available for narrowing your search. The top of that panel shows a button that will clear all filters. Currently, it shows that we have three filters engaged. The action bar here includes a Download button that allows you to download the search results in text, CSV, or JSON. In CSV you can select from our most popular fields. Or in JSON you can download all publicly available data. The cards themselves include key information such as title, the study status, if the study has study results, and the site locations. Here's what it looks like if it has multiple sites. These

are listed alphabetically by state, then city, and locations within the United States are always shown first. Clicking on Show all locations will take you to that section of the study record. The same applies for the results button. Clicking "WITH RESULTS" will take you to the results section of the study record. Now I'm going to show you a table view of the search results.

In this view, the filters are not immediately available, but you can still find them under Narrow Your Search. In this view, we have horizontal scrolling as well as vertical scrolling. And as you scroll down the page, a button becomes available in the bottom right-hand corner that allows you to immediately scroll back to the top of the page. Now I'm going to show you the study record page.

You can see key information is available at the top of the page such as the title, the study status, the responsible party, and the date the record was last updated. As you scroll down, you'll see that study record dates are available and we have a left-hand navigation panel, which allows you to move throughout the record. Now I'll go to the contact and location section.

In Contacts and Locations, you'll see the list of study sites on the left-hand side of the card and a map on the right-hand side. The map uses Google Maps API integration. Clicking on a site in the list . . . zooms the map into focus on that site location. If the study were still recruiting, you would see a central contact and/or contacts for each of the clinical site locations. If we go back up the study record, you'll see the action bar has a Download button for single study download. This is available in CSV, JSON, and FHIR JSON. And to the right of the Study tab, you'll see that results are available in another section of the study record. And that concludes our demonstration of the beta ClinicalTrials.gov website.

All right. I hope that was a helpful demonstration. As you're able, please visit the website and explore. That was simply an overview of some of our key features. There's lots more and we do want to hear how it's functioning for you. What you see now is a high-level overview of the features that are already available, those that are in progress. You can see that we have started work on a tabular view of study records and an improved version of the study record history, content migration and information architecture, as well as development of support materials. In the future, in the coming months, we will begin work on a beta API, download to XML; we want to make connections available to trusted health information as well as the next steps to join a study for our patient users. We know that the majority of them come to ClinicalTrials.gov hoping to join a study. So we'd like to make that just a little bit easier if we can. And, finally, onboarding users. Often, patient users, caregivers, members of the public will do a search for studies in a particular disease area, for an illness or injury, and they might land on the study record page, for example. And so we want them to know, regardless of how they come to the website, where they are and what they can do here.

I mentioned earlier that we do have a Release Notes page. You can see here that that will provide a summary of the new functionality and any improvements that we've made available with each of the releases. Those are available chronologically going back to launch of the

website in December of last year, and you can find that in the top right-hand corner of the site menu under the About section.

Next, I want to point out that we have ongoing user research. We are looking closely at traffic and feedback on the website as we continue to build. This is really the time, before the beta website becomes primary; we want to hear what's working, what's not, and how we might be able to improve it. And to that end, we are looking for folks to help us out, volunteers to give feedback, to participate in different activities. We want to hear from patients, caregivers, pharmaceutical administrators, academic administrators, research coordinators. If you fall into any of those groups or any of the groups listed here, please reach out to us and let us know that you would like to help improve the website. There's a variety of tasks that you might be asked to participate in, and those can last anywhere from 15 to 60 minutes. Some are done in person, but they are done virtually, I will say. Some are done on your own time as you're able. And the best way to do that is to give feedback through the website.

In the bottom right-hand corner of every page on the beta website, you'll see a green button that says, Give us feedback or Give feedback. Just submit a comment there, with your contact information, and let us know that you want to volunteer for the user research on the beta website. We would be most grateful. And I believe with that, Anna, I will hand control back to you.

Thank you, Ms. Robinson, for the beta demonstration and for all those updates. I'll welcome both Dr. Dharker and Ms. Robinson back shortly for our Q&A. So keep those questions coming, again, in the Q&A box.

So overall, the modernization roadmap expects the ClinicalTrials.gov Beta website to assume the main URL sometime next year. The PRS is on a longer timeline, with plans to release the registration module in 2023 and the result submission module in 2024. Our engagement efforts remain a priority. We'll continue to provide you with updates, and I'll explain further how you can stay informed.

This fall, we plan to release a report summarizing in detail all the progress from this year. We provided a report last year summarizing the first two years of the modernization effort. So much progress has been made since then. So rather than wait another year, we've made this report annual and we'll be releasing it soon. So that will also be coming out through our web updates and Hot Off the PRS! And I'll talk about that in just a second.

And you can stay up to date through a variety of mechanisms, whether it's through social media, webinars such as these, or coming to our webpages. We welcome input on what more we can do to keep you informed of changes. So even if you don't have a question, please do feel free to put some feedback into the Q&A box and let us know if there's other things we can do, conferences we should be at. We want to make sure the stakeholders are up to date and getting the information that they need.

We will make the slides and the recording available. It will take a little time, of course, for us to ensure proper compliance with closed captioning and 508 compliance. You can sign up to receive a direct email from our Hot Off the PRS! newsletter that is sent directly to you when updates are available. And I'll invite my colleagues back now to answer some of your questions as time permits. So please stand by as we transition to reading some of the questions.

Welcome back, Dr. Dharker. And we're still waiting for Ms. Robinson. There we are. Welcome back. So thank you again for all your questions. Just give me a minute as I read through. But I see that there is many of them and we're so excited to take them. So let me just start with a question for I believe this would be for Christina. Are there any plans to changes of, to History of Changes? And when will we be seeing those?

Great question. Thank you so much for that. I will say that we do hope to make it more functional. We do hope to improve over the History of Changes that is available on the classic website at this time. You can get to a study's record history from the beta website, but we are working, actually right now, on a record history for the beta website and we do hope to offer some additional functionality there.

Great. Thank you. We have another question here, which I think is for you, Nachiket. Will old study records need to be changed because of modernization?

That's a great question, too. Users will not need to make any changes to their existing records as, as a result of Protocol Registration and Results System Beta releases. So just to clarify, this is a technology update. The modernization effort will have no impact on existing reporting requirements. And ClinicalTrials.gov is not planning on adding a new data element or new data elements as part of modernization. I hope that answers that question.

Thank you. We have a number of questions here about the JSON API and just API in general. Christina, could you address that? Will the API be changing?

Yes, we do suspect that the API will change. When it is made available, it will be available as a beta version. The API, the current API will still be available. We will make sure that we communicate all of these things and allow ample time first for feedback on the beta, the new beta API, and then to allow for a transition period. So anyone using the current API will have time to make that transition. Once we do make that available, please offer feedback because again, we want to continually improve and make things better for our users.

Thank you, Christina. Nachiket, I believe this is a very specific question for you regarding the PRS. If you move columns around, is that view maintained in the downloads? Maybe that's for you, Christina.

I'm sorry. Can you repeat that question?

When the columns, and I'm not sure which specific columns, but when columns are moved around, will that view be maintained in the downloads?

Yeah. I'm not entirely sure if that's referring to the website or to PRS. I can't answer that question at this time. We do have download available. You can adjust the, the data that is part of the download. I, you can't at this time adjust the order of the data that is downloaded. That's an interesting question. I'll have to see if that's technically feasible before I can answer a question about whether or not to make that available. I, I would say if, if the question was for specifically was for PRS, then ideally one should be able to maintain the order or the, the customized display that you have selected while rearranging or reordering the columns. Again, as I said, we are continuously improving and enhancing the current functionality of the Record List and also identifying issues with the existing parts that we have released and correcting them. So stay tuned and if, keep trying, and if you notice that it is not functioning that way, please provide us the feedback, and we'll definitely consider that.

Thank you. So, Nachiket, I think this question's for you: Will it be possible to upload XML files of study records, or are there any changes or work being done on XML?

Yeah. No, we absolutely are going to continue providing XML upload options so that, I know a lot of users use that or need that. So we are, we are going to continue having that. How we in or in what capacity or what if we are going to make any changes? At this time, we are, as I said, we are focusing on protocol registration, data entry, or the user experience. So we are still to kind of fine tune and decide exactly what that change, if any, is going to be. But to answer the question, yeah, we are going to continue offer, continue to offer that function.

Thank you. So, Christina, I think I have a two-part question here. A few questions are coming in asking about when will the classic site go away. And another part to that question is will the modernized ClinicalTrials.gov site get a new name?

Thank you for that question. So, as Anna mentioned during her final slide presentation, the beta website will become the primary website at some point next year. We will not retire the classic ClinicalTrials.gov until we know that the beta website is fully functional for our users. That currently is to be determined. I think that will probably be based on a combination of traffic, those users returning to the classic ClinicalTrials.gov, and the feedback that we're getting on the beta website to make sure that users can accomplish the, the necessary tasks there. I think the second part of that question had to do with ClinicalTrials.gov getting a new name. No, it is ClinicalTrials.gov, and it will continue to be ClinicalTrials.gov.

Thank you. And I think I have another question. This kind of relates to both of you, I believe, front end and back end. So while the classic site's available, will records created or changed in one version appear in the other? So what am I seeing going to beta and what am I seeing if I go to classic site?

Nachiket, I, if you don't mind, I'll go ahead and take that. So, yes, anything that is released in PRS to the website will be available on both classic and the beta website. We are already pulling the data, the study record data, on a daily basis from the PRS. And so you will see those changes in both environments.

Great. Keep, I would also add to that for even, for the PRS system, what we are aiming for is whatever features we are providing, let's say if you are creating new records when, when the protocol registration is available next year, let's say if you create new records with, starting with beta and using the beta screens, those will be actually saved so users can go and actually work on their records, and then for the functionalities that would, are still not available or will still not be available, they will need to use the classic PRS. And we are thinking and discussing ways, how we can make that transition between the classic versus beta as seamless as possible. But again, users will be able to go back and forth between those.

Thank you for that. I think this question would also go to you, Christina. When someone registers a new study, will the beta website automatically update the maps for locations?

Yes, that is correct. I will say that the accuracy and functionality of the map is dependent on the data that is entered. But if, if you release a study that includes location information, the map will automatically appear and be updated. That functionality includes adjustments based on location information that users enter in their search. So, for example, if I look for studies in Washington, D.C., and I go into a study record, I'm going to see the, the sites that are in or near Washington, D.C. If you don't enter location information, then you're going to have a view of all of those study sites.

Great. Thank you. Nachiket, I believe this question's for you, and I don't know if it's more feedback or if you actually might have some insight into this. But do you plan on making the highlighted differences available to view before clicking Release?

Great feedback. Thanks for providing that. And it is, we have received that feedback I think earlier, also. So we are definitely considering that. Again, right now, as of now we have not reached that stage, but we'll definitely keep that in mind. Thanks for that.

I think this is another feedback. We have a question about planning any Train-the-Trainer support to help responsible parties and vendors disseminating PRS modernization further throughout their organizations. I think that's really great feedback. I mean, I can help take that. Yes, we do want to make sure that we're supporting our data providers and supporting our users as we are also working equally, very busy behind the scenes, maintaining both the PRS and the PRS Beta and the ClinicalTrials.gov and the ClinicalTrials.gov Beta. But as new information becomes available, we do want to make sure that we're updating our resources, our trainings, our videos and hope that we can, of course, do some of those Train-the-Trainers in person again soon. So that's great feedback as well.

I think there's a couple questions here, and I can answer them to the extent that they relate to modernization as well and, Nachiket, you might be able to support me. There's some questions here regarding just record management when it's an ACT or an NIH record. And I think this was feedback that we also received through the RFI. So we've been asked if it's possible to let administrators or also responsible parties know when their record might need to be updated or is coming up with some pending deadlines. So right now you do receive a problems report, but

that problems report, of course, isn't as timely as I think people would like. And so we're very much aware of that feedback. And I believe it's something that, Nachiket, you hope to work on in the future to incorporate into the new beta. But I'll let you speak to that as well.

Yeah, absolutely. This is, as you said, Anna, we have, we are aware of this feedback. We have received it previously, so it is definitely in, is something that we will consider and try our best to kind of implement. It's basically, as you said, Anna, how, how we can make the notifications better so that we can help the, all our data submitters and users in a better way. So absolutely, yeah, definitely we will consider this and hopefully we'll be able to provide that kind of support.

Great. Thank you. Christina, we just had someone else type in a question asking if you can repeat the information about API and Excel.

Yes. So we already have download available in CSV format. We are currently working on the beta API. We do anticipate making the first version of the beta API available in the coming months.

Great. Thank you. Are all studies that are available at ClinicalTrials.gov now also uploaded in beta ClinicalTrials.gov site?

I'm sorry. Can you repeat that?

Are all the studies that are uploaded or are in ClinicalTrials.gov also available on the beta website?

Yes. Yes. We are, anything that is live on the classic ClinicalTrials.gov is available on beta.

Okay, great. So thank you for bearing with me as I read through some of these questions, making sure that we get to them all. So I think there's a lot of questions still around upload and I'm not sure if there's more that you can say, Nachiket, in terms of other areas that you would consider being able to upload templates.

Yeah. That is something. Excuse me. That is something that we'll have to explore when we reach the point where we are ready to work on the results submission. Because most of this is, I think, as the question pertains, has to do with the results reporting. And again, at this time, because it's for us, it's right now not very close at that point. So we are still not sure about this. But again, thanks for the feedback and we'll definitely consider this. I have also heard I mean, this is also one of the feedbacks that we have received previously. So we are aware of this.

Great. Thank you. And Christina, I think you talked about this a little bit, in terms of History of Changes, but I just want to make sure if we need to reclarify. It looks like there'd be a desired feature to have a highlighted comparison of the History of Changes. So would that be available in beta version?

So yes, we will be making available the Compare feature. We have that already on the classic ClinicalTrials.gov and you will be able to compare a couple of versions on the beta website as well.

Great. Thank you. I know there's another question here, I, I think it is related to the problems. If a record has errors, will there be little more notification that could be provided versus just, hey, your record has errors, please log in? And I'm not sure if we can answer that yet, but I think it's really great feedback. I'm not sure if there's anything else you want to add to that, Nachiket?

Yeah, I agree. That's a great feedback. Again, and that kind of falls into the category or the bucket of notifications and how we can improve the notifications and our messaging to the , to our users. So we'll definitely consider that.

Great. Okay. Now, I know we've really exhausted a lot of your time. I promised my speakers they wouldn't get too many questions, but these are great, and we really appreciate you having them here. I do think some of the questions that are coming in, it's more feedback. You're asking for very specifics. And as I think Nachiket has indicated, it's still another year or two before the PRS is available. And I believe there was a question here that asked when you'll be able to actually, in its entirety, be able to use it. So the protocol registration, we do hope to be available sometime next year and you'll already start seeing parts of it in PRS Test soon, and then the results feature will not be for at least another year. So some of these specific questions on will I be able to do this? Or certain actions, I don't want to promise anything. We want to hear what you're looking for and it's really helpful for us. So that's where I'm looking at some of these questions. Thank you for them. It's actually good feedback, what you're looking for and we're going to be downloading all of these and reviewing them. So thank you for that.

So I'm just checking if there's anything else that came into the box that we might be able to provide more details on. There is a question about plain language, but it's not very specific. More details on what we can do for sharing plain language. So I believe Christina had noted that some of the webpages now on beta, we did ensure that they were reviewed to be as plain language as possible and helpful for all users, especially our patients, especially just what is a clinical trial and how do I enroll? And what should I think about when I enroll? So that's one example. And then also the help text that I believe Nachiket was sharing that we're putting into the PRS, these drawers. We're reviewing some of the glossary terms and text that we have to make sure that that's also as plain language as possible. Because I know it's very complicated. So that's some of the efforts that we have in plain language, and I could probably take that one step further. We did recently release, in September, a checklist for plain language to support some data providers now, because we were reviewing it for modernization and building these help features. We figured, why not put it out there in PRS now? And if you have feedback on that, we can make it even better before it's rolled out into the PRS Test and into the PRS Beta. So there's questions on that.

And then, it just one more question came in now about any plans again for uploading locations and data in the protocol using an Excel sheet. So I think, Nachiket, you've touched a little bit on this. People really love that adverse event Excel upload feature. So that's great feedback and anywhere else, whether it be locations or other . . . pieces of information that could be made easier and automatically upload. It sounds like that's what people are looking for. So feedback for you on that.

And then, Christina, maybe you could just speak to this a little bit about linking to published articles and resources, especially like PubMed and PMC. Is there anything you'd like to comment on that?

Yeah, absolutely. We do this already on both the classic ClinicalTrials.gov and beta. The publications are entered by the record owner. So anything that they've entered, and those are marked as either being general or refer, referring to the results of the trial. We automatically index anything in PubMed that includes the identifier, the NCT or national clinical trial number. Any publication that includes that NCT Number is automatically indexed and shared as part of that study record. So that information is actually already there. So, please feel free to take a look, see if that meets your needs and if not, give us some feedback on it.

Christina, just maybe to clarify, someone might have heard that you mentioned an initiative about helping connecting patients to trials. I'm not sure if we need to clarify what we meant by that statement.

Yes. So we do know that patients, when they come to ClinicalTrials.gov want to join a study. And so we're going to be investigating the possible ways that we can help them do that. We obviously can't endorse a particular study or tell users of our website that they should join a study. But if that is their intent, if that is their interest, then we want to make that possible for them. And so we're going to be doing some investigation into what is possible on ClinicalTrials.gov.

Great. And I think you've done a little bit of that now, Christina, too, with some of the records in terms of information that the patients are really searching for: who to contact if they want to go to a study, what are the locations and the features. So I think that's sort of what we mean by that as well, making sure that that content is easily retrievable that patients are looking for.

And I think that I know we're running out of time here, so I will probably just take a pause at this moment. We do appreciate your questions. Like I said, we will review them. If there's some that we haven't answered, we'll make sure we try to address some of them in the future and in our communications. But I want to take our two speakers off the hot seat. I appreciate you taking a good 15 to 20 minutes to take these questions. So thank you for our attendees. We really appreciate this. It's really great to be able to come, to connect with you and hear from you directly. So that's all the time we have today. Thank you again to my speakers and the amazing teams behind them. And to our attendees, thank you for joining and for all your questions. So this concludes today's webinar. Goodbye and until we meet again.